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(54) **OPIATE REDUCTION TREATMENT SYSTEM**

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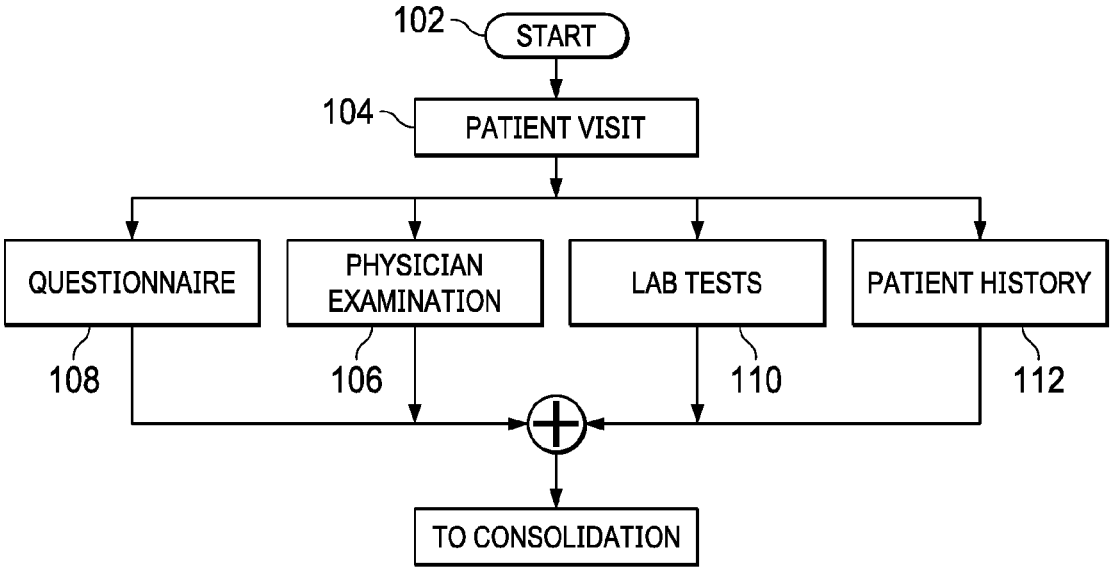
(57) **ABSTRACT**

This disclosure relates to an opiate reduction treatment system. The system comprises a PIN generator for creating a Patient Identification Number (PIN) unique to a given patient, wherein the PIN includes one or more fields, and wherein the one or more fields each include a scored value, each scored value associated with a defined portion of a health profile of the given patient, a database including test results for a plurality of PINs, and known treatments, and a neural network, including an input layer configured to receive an output of a PIN for a given patient from the PIN generator and compound constituents as input values, an output layer configured to provide an opioid reduction treatment prediction, an intermediate layer configured to store a representation of the database, and map the input layer to the output layer through the stored representation.



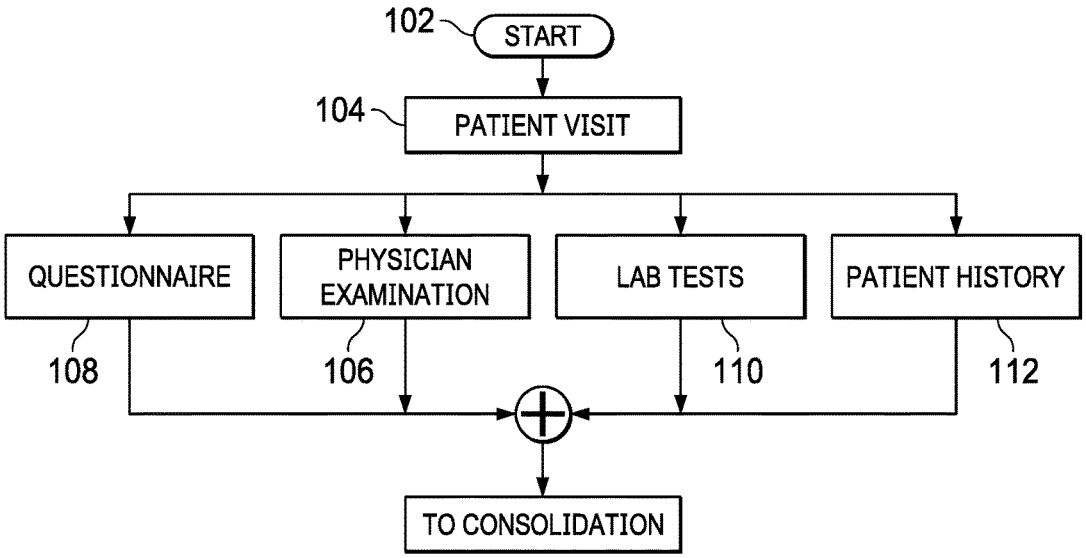

102
START
104
PATIENT VISIT
QUESTIONNAIRE
PHYSICIAN EXAMINATION
LAB TESTS
PATIENT HISTORY
108
106
110
112
TO CONSOLIDATION

FIG. 1

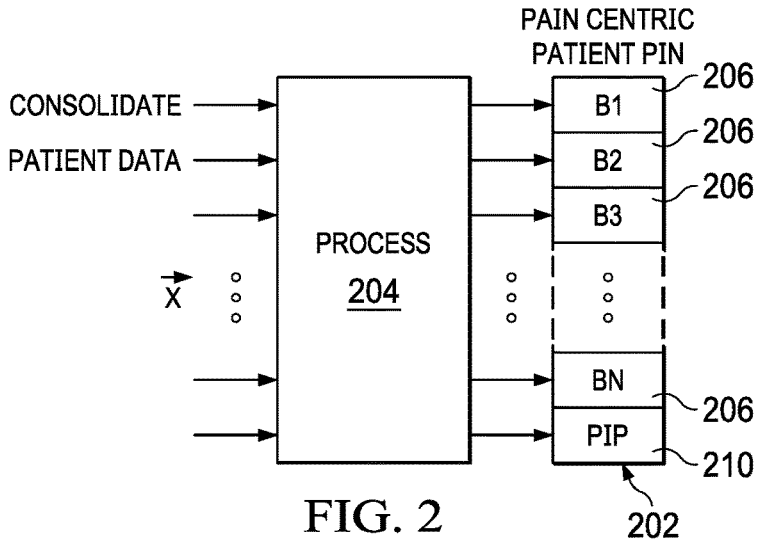

PAIN CENTRIC PATIENT PIN
CONSOLIDATE
PATIENT DATA
X
PROCESS
204
B1
B2
B3
BN
PIP
206
206
206
206
210
202

FIG. 2

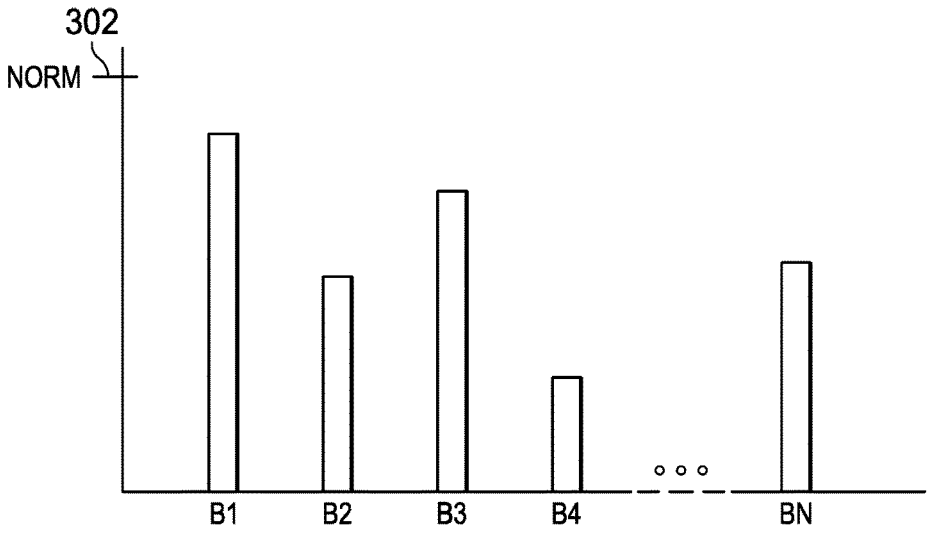

302
NORM
B1
B2
B3
B4
BN

FIG. 3

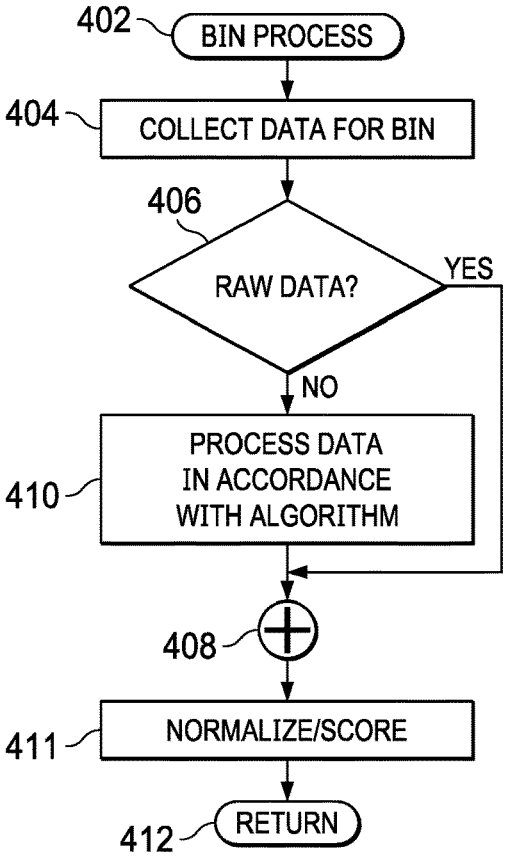

402
BIN PROCESS
404
COLLECT DATA FOR BIN
406
RAW DATA?
YES
NO
410
PROCESS DATA IN ACCORDANCE WITH ALGORITHM
408
411
NORMALIZE/SCORE
412
RETURN

FIG. 4

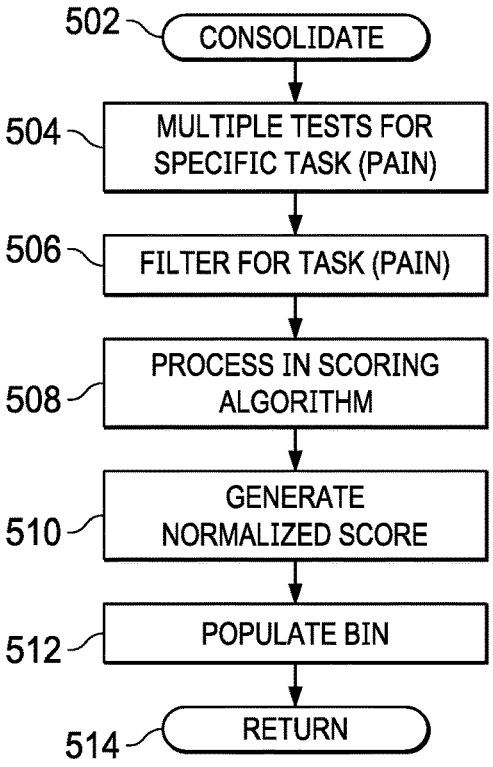


FIG. 5

LIVER PANEL

TEST	RESULTS	NORMAL	PAIN SPECIFIC WEIGHT	SCORE
ALT	...	...	0-1	1-10
ALP	...	...	0-1	1-10
BILIRUBIN	...	...	0-1	1-10
⋮	⋮	⋮	⋮	⋮
				$\overline{\text{AVERAGE SCORE (NORMALIZED)}}$

FIG. 6

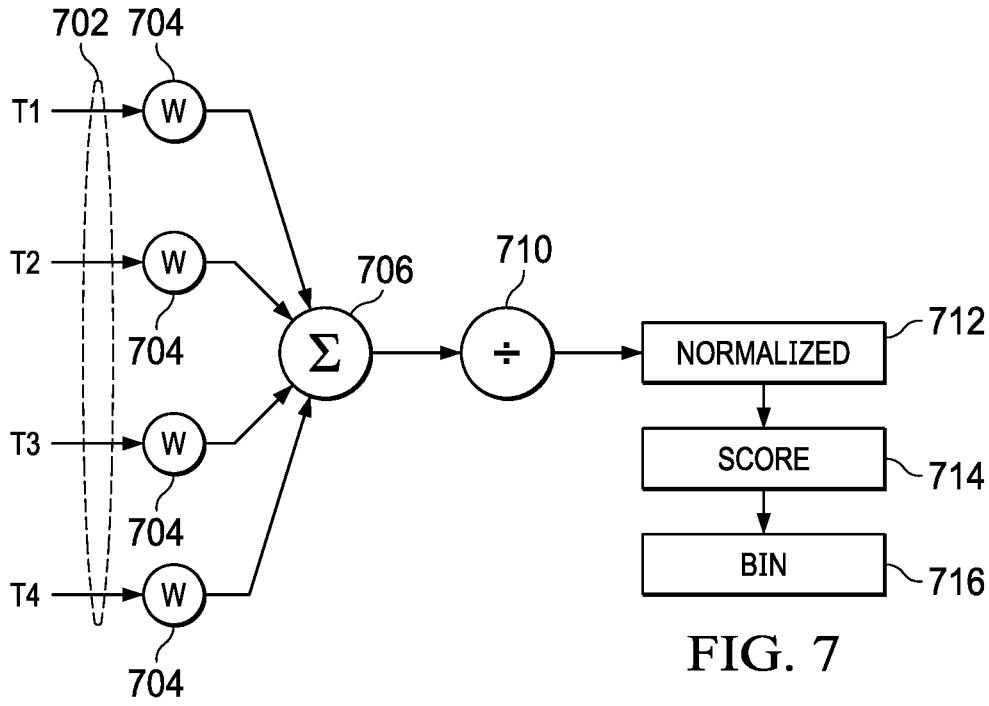

702
704
T1
W
T2
W
704
706
710
T3
W
704
T4
W
704
Σ
÷
NORMALIZED
712
SCORE
714
BIN
716

FIG. 7

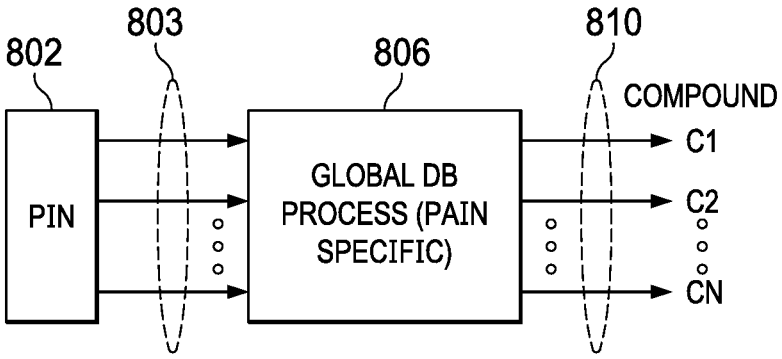

802
803
806
810
PIN
GLOBAL DB
PROCESS (PAIN
SPECIFIC)
COMPOUND
C1
C2
CN

FIG. 8

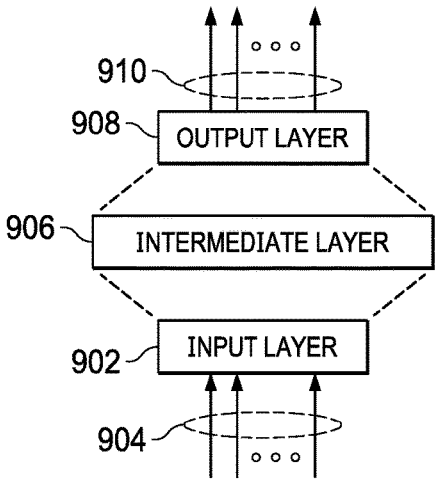

910
908
OUTPUT LAYER
906
INTERMEDIATE LAYER
902
INPUT LAYER
904

FIG. 9

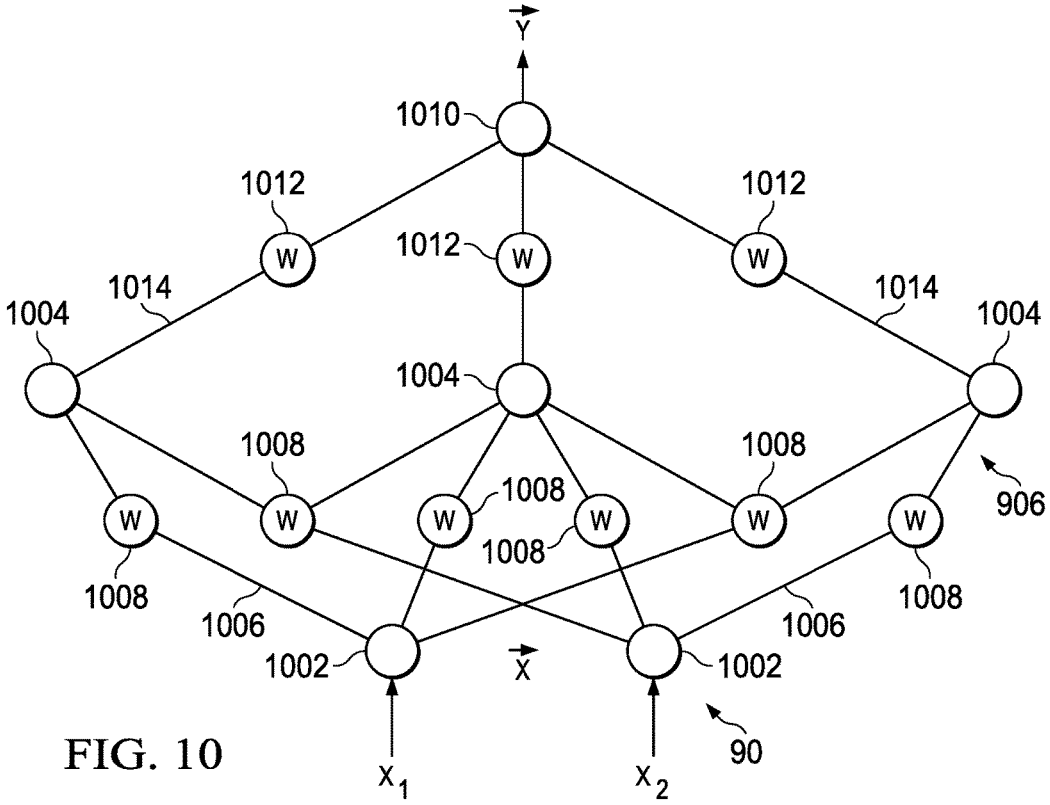

Y
1010
1012
1012
1012
W
W
W
1014
1014
1004
1004
1004
1008
1008
1008
1008
W
W
W
W
W
W
906
1008
1008
1006
1006
1002
X
1002
90
X1
X2

FIG. 10

OPIATE REDUCTION TREATMENT SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 62/482,040, filed on Apr. 5, 2017, entitled OPIATE REDUCTION TREATMENT SYSTEM (Atty. Dkt. No. RCMD-33519) which is incorporated by reference herein in its entirety.

TECHNICAL FIELD

[0002] The following disclosure relates to opioid abuse and systems and methods for reduction of the use of opioids.

BACKGROUND

[0003] Opioids are medications that treat pain in many contexts, from post-surgical relief to chronic severe back pain and of-like care. Two of the most common forms are oxycodones, often sold under the brand names OxyContin® and Percocet®, and hydrocodones, sold as Vicodin®. Both are powerful narcotics. Americans are the number one consumer of these drugs, accounting for almost 100 percent of the hydrocodone prescriptions and 81 percent of oxycodone prescriptions worldwide. In the United States, more than 2 million people are addicted to these medications.

[0004] These drugs became more readily available to patients in the late 1990s, and prescription rates nearly doubled between 1998 and 2013. This epidemic is the unintended consequence of policy and practice that was supposed to benefit patients and keep them safe. A solution to this kind of systemic problem that affects the health, social, and economic welfare of society requires a large-scale, comprehensive course of action. The healthcare delivery system is ground zero.

[0005] The result in recent years is opioid overuse and over prescription. However, pain relief is critically important to a number of patients and the use of opioids in relieving this pain is the primary avenue chosen by most physicians. The problem facing healthcare industry is: too little pain relief and millions will suffer; too much and lives are at risk. The challenge facing the healthcare industry is to solve this problem and, at the same time, realize a significant reduction in opioid use.

SUMMARY

[0006] In one aspect thereof, an opiate reduction treatment system is provided. The system includes a PIN generator for creating a Patient Identification Number (PIN) unique to a given patient, wherein the PIN includes one or more fields, and wherein the one or more fields each include a scored value converted from raw data corresponding to one or more test results, each scored value associated with a defined portion of a health profile of the given patient, a database including test results for a plurality of PINs for a plurality of patients and associated compound constituents provided to each of the plurality of patients, and known treatments, and a neural network, including an input layer configured to receive an output of a PIN for a given patient from the PIN generator and compound constituents as input values, an output layer configured to provide an opioid reduction treatment prediction, an intermediate layer configured to store a representation of the database, and map the input layer to the output layer through the stored representation.

[0007] In one embodiment, the scored value is created from one or more inputs from the raw data that are weighted according to associated test types and normalized.

[0008] In one embodiment, the one or more fields of the PIN includes a code assigned to a patient.

[0009] In one embodiment, the code assigned to the patient is a Patient Information Profile (PIP), wherein the PIP identifies the patient.

[0010] In one embodiment, at least one of the one or more fields of the PIN corresponds to a particular test.

[0011] In one embodiment, at least one of the one or more fields of the PIN corresponds to a compound formulation.

[0012] In one embodiment, the scored value is a value within a number range.

[0013] In one embodiment, the number range is a range between 1 and 10.

[0014] In one embodiment, the PIN represents a patient pain profile at a first point in time.

[0015] In one embodiment, the neural network is further configured to receive an output of another PIN representing a patient pain profile at a second point in time, predict another opioid reduction treatment using the other PIN, and store a revised treatment plan in the database.

[0016] In another aspect thereof, a method for providing an opiate reduction treatment is provided. The method includes generating a Patient Identification Number (PIN) including one or more fields, collecting raw data corresponding to one or more test results, converting the raw data into a scored value, storing the scored value in one of the one or more fields of the PIN, predicting an opioid reduction treatment for a patient, including providing as input values an output of the PIN and compound constituents to an input layer of a neural network, applying, by an intermediate layer of the neural network, the input values and compound constituents information to a stored representation of a database, wherein the database includes test results for a plurality of PINs for a plurality of patients and associated compound constituents provided to each of the plurality of patients, and generating, by an output layer of the neural network, an opioid reduction treatment prediction, and delivering to a patient an opioid reduction treatment corresponding to the opioid reduction treatment prediction.

[0017] In one embodiment, converting the raw data into the scored value includes creating one or more inputs from the raw data, applying a weight to the one or more inputs to generate one or more weighted results, each one of the one or more weighted results corresponding to one of the one or more inputs, summing the one or more weighted results to generate a summed output, dividing the summed output by a number of tests to generate a result, and translating the result into the scored value.

[0018] In one embodiment, the one or more fields of the PIN includes a code assigned to a patient.

[0019] In one embodiment, the code assigned to the patient is a Patient Information Profile (PIP), wherein the PIP identifies the patient.

[0020] In one embodiment, at least one of the one or more fields of the PIN corresponds to a particular test.

[0021] In one embodiment, at least one of the one or more fields of the PIN corresponds to a compound formulation.

[0022] In one embodiment, the scored value is a value within a number range.

[0023] In one embodiment, the number range is a range between 1 and 10.

[0024] In one embodiment, the PIN represents a patient pain profile at a first point in time.

[0025] In one embodiment, the method further includes providing an output of another PIN representing a patient pain profile at a second point in time, predicting another opioid reduction treatment using the other PIN, and storing a revised treatment plan in the database.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] For a more complete understanding, reference is now made to the following description taken in conjunction with the accompanying Drawings in which:

[0027] FIG. **1** illustrates a flowchart for the initial patient visit;

[0028] FIG. **2** illustrates a diagrammatic view of the overall process for creating a Pain Centric Patient PIN;

[0029] FIG. **3** illustrates a histogram for creating binned values for populating the Pain Centric Patient PIN;

[0030] FIG. **4** illustrates a flowchart for the Bin process;

[0031] FIG. **5** illustrates a flowchart for the consolidation operation;

[0032] FIG. **6** illustrates a diagrammatic view of one set of test results that are used to generate a value for the binning operation;

[0033] FIG. **7** illustrates a diagrammatic view for the consolidation operation to normalize multiple tests into a score;

[0034] FIG. **8** illustrates the operation wherein the PIN is mapped through a model of the compounding process;

[0035] FIG. **9** illustrates a diagrammatic view of a non-linear network for realizing the overall model; and

[0036] FIG. **10** illustrates a schematic view of a neural network.

DETAILED DESCRIPTION

[0037] In order to reduce opioid use, other compounds are resorted to. These involve, in some cases, topical analgesics which are used to reduce systemic exposure to opioids, limit side effects, and lower the risk of drug-drug interactions. The goal of utilizing these alternative or other compounds is to improve tolerability and reduce overall opioid use—all while managing primary pain symptoms. However, most people with chronic pain have a desire to do anything possible to get rid of the pain. Their first introduction to any pain medication in the healthcare system will be through their primary physician and, even though they may come to the physician asking for a particular medication by name or simply asking for the strongest drug they are offering, the healthcare system has a desire to reduce the influence of pain as opposed to getting rid of the pain, through such things as providing patients with realistic expectations and teaching acceptance of pain itself. However, pain medications in the form of opioids will still be a mainline treatment.

[0038] Referring now to FIG. **1**, there is illustrated a diagrammatic view of the first step in determining what compound possibly might be useful to achieve opioid reduction. The primary interface to the medical system will be the primary physician. The primary physician can evaluate a particular patient through a physical exam, evaluating drug tests that are specifically focused on drug use and pain, keeping in mind that each patient is unique in their source of the pain and in their therapeutic regimen that they may follow. In addition, this can change over time as a result of using opioids, understanding that chronic pain is very closely tied with the interplay of various physical limitations, psychosocial sequelae, personality predispositions, stress, medical uncertainty, and personal coping resources.

[0039] Initially, the process is initiated at a block **102** and proceeds to a block **104** which represents the overall patient visit, the first interface of the patient to the healthcare system. In this patient visit, and specifically one with the purpose of reducing opioid use, it is recognized that the patient uses some form of opioid at some level. The physician at this point utilizes a physical examination of block **106**, a questionnaire at block **108**, lab tests at block **110**, and patient history at block **112** in order to collect data on a particular patient at a particular time. This will allow a profile of the patient to be determined. And this profile will be altered somewhat by the results of some of the lab tests and some of the results of the physical examination. This examination may be physical, and it may be psychiatric in order to address various comorbid states, such as depression, anxiety, and post-traumatic stress disorder. Chronic pain and depression, in particular, are intense bedfellows.

[0040] Referring now to FIG. **2**, there is illustrated a diagrammatic view for the process of taking the consolidated patient data collected in the patient visit and processing it to provide a condensed and more focused profile of a particular patient. This profile will result in a unique Patient Identification Number (PIN). This is illustrated in a block **202**. The process is illustrated at block **204**. This process basically takes all the data that can be provided which is an ordered set of data and is designed to collect data primarily for the purpose of determining factors that relate to patients with chronic pain. For example, one of the first steps of screening a chronic pain patient is to collect data made during a brief psychosocial screening which asked the following questions:

[0041] Activities: how is your pain affecting your life (i.e. Sleep, appetite, physical activities, and relationships)?

[0042] Coping: how do you deal/cope with your pain (what makes it better/worse)?

[0043] Think: do you think your pain will ever get better?

[0044] Upset: have you been feeling worried (anxious)/depressed (down, blue)?

[0045] People: how do people respond when you have pain?

[0046] In dealing with the overall interview, a Standardized Pain Assessment can be performed which has been developed to evaluate patients' attitudes, beliefs, symptoms, motions, quality of life, and expectancies about themselves and the healthcare system. These, of course, can change every time a patient visits the physician's office. These are shown in the following table:

Sample of Standardized Tools for Chronic Pain Assessment

[0047]

Measure	Number of items	Domain assessed
Unidimensional pain measures		
Numerical Rating Scale (NRS)	1	Pain intensity using a numbered scale (e.g. 0-10, 0-100)
Verbal Rating Scale (VRS)	1	Pain intensity using verbal descriptors (e.g. mild, moderate, severe)
Visual Analog Scale (VAS)	1	Pain intensity using 10 or 100 mm line, anchored by no pain and worst possible pain
Facial Pain Scale (FPS)	1	Pain intensity using a range of facial expressions
Pain thermometer	1	Pain intensity using a depicted thermometer to rate pain
Pain quality and location		
McGill Pain Questionnaire (MPQ)	20	Pain quality, location, exacerbating, and ameliorating factors
Short-form-McGill Pain Questionnaire-2 (SF-MPQ-2)	22	Pain quality, location, exacerbating, and ameliorating factors
Neuropathic Pain Scale (NPS)	10	Neuropathic pain qualities
Regional Pain Scale (RPS)	19 Sites	Extent of body pain
Pain interference and function: general		
Pain Disability Index (PDI)	7	Pain disability and interference of pain in functional, family, and social domains
Brief Pain Inventory (BPI)	32	Pain intensity and interference of pain with functional activities
PROMIS pain interference and pain behaviours item banks	Interference Bank = 41; Behaviours Bank = 39	Pain interference and behaviours related to the impact of pain
Functional Independence Measure	18	Physical and cognitive ability, burden of care
Pain interference and function: disease specific		
Western Ontario MacMaster Osteoarthritis Index (WOMAC)	24	Pain and function in people with osteoarthritis
Fibromyalgia Impact Questionnaire (FIQ)	20	Health status for people with fibromyalgia
Roland-Morris Disability Questionnaire (RDQ)	24	Pain and disability for people with back pain
HRQOL		
Medical Outcomes Study Short Form Health Survey (SF-36)	36	Mental and physical health
West Haven-Yale Multidimensional Pain Inventory (MPI)	60	Pain severity, interference, mood, activities, sense of control, support, quality of life
EuroQOL (EQ-5D)	5	Health status, pain, and mood
Sickness Impact Profile (SIP)	136	Physical and psychosocial dysfunction
Psychosocial measures		
Beck Depression Inventory (BDI)	21	Depressive mood
Profile of Mood States (POMS)	65	Mood and emotional functioning
Symptom Checklist-90 Revised (SCL-90R)	90	Multiple domains of psychological functioning
Pain Catastrophizing Scale (PCS)	13	Catastrophic thoughts related to pain
Coping Strategies Questionnaire (CSQ)	10	Coping strategies for chronic pain
Observational pain assessment		
Pain Behaviour Checklist (PBC)	16 Categories	Observational measure to assess patient's pain behaviours

-continued

Measure	Number of items	Domain assessed
Real-time assessment of pain behaviour	5 Categories	Real-time assessment of pain behaviours integrated with a standardized assessment

[0048] The patient can also be asked to assess the pain intensity via a self-report measure, report the pain quality and pain location in addition to the pain intensity, the pain interference with function and quality of life, the emotional distress and coping issues that the patient may be undergoing, the overt expressions of pain, etc. All of these responses will provide valuable information to the patient profile. However, the correlation in this data is of such nature that certain tests in certain responses to questions and the such had a higher weight in the decision-making process as to the reduction of opioid use. This also greatly affects the combination of opioid use with alternative compounds, and it also, as will be described hereinbelow, will affect the determination of what compound formulation will correlate with the highest degree of opioid reduction. It may be that a patient can function with a 60% opioid reduction by substituting a particular compound formulation involving such things as topical analgesics and the such. It is the determination of this compound formulation that will be determined by the system and method set forth hereinbelow. However, once the particular tests and assessments that relate to chronic pain have been determined to be important, they can be reduced to just the raw values or two normalized values that can be placed in various bins associated with various fields in the patient PIN. This patient PIN is a Pain Centric PIN for a particular patient. There is one field that provides a unique code for the patient, a field **210**, which is a Patient Information Profile (PIP). This is the basic patient profile that does not change. This will identify the patient, whereas the Patient Centric Patient PIN **202** identifies the patient profile at a particular time associated with chronic pain as experienced by the patient at that particular time. This chronic pain may vary as a result of the pain medication the patient has been taking, the mental attitude of the patient, or other external things that have changed in the patient's life since, for example, the last time that the patient had been profiled from a patient centric point of view.

[0049] FIG. **3** illustrates a histogram illustrating how the values in the bins **206** are distributed. All of the values, in this example, are normalized to a value **302**. They could, of course, be the actual values. Each of the bins will have a different value associated therewith, resulting in a unique code for that particular patient at that particular time from a pain centric point of view. This particular unique code will probably change each time the patient is evaluated. A number of the bins could actually be associated with the actual drugs or compound formulation that the patient is currently taking.

[0050] FIG. **4** illustrates a flowchart depicting the overall binning process, which is initiated at a block **402** and then proceeds to a block **404** wherein all of the data is connected for a particular bin. The program then proceeds to block **406** to determine if basically the raw data from the test or the questionnaire is to be input to the associated bin. So, the program flows to the input of a summation node **408** and, if not, the program flows along a "N" path to a function block **410** in order to process data in accordance with a predetermined algorithm or some type of consolidation process. The program then flows to a function block **410** to normalize/score a particular value. The term "score" refers to a process whereby a group of tests or answers to questions may be evaluated and given a final value of between 0 to 10, for example. It could be that all of these questions answered by the patient in the written assessment are lumped together, each given a weight and then summed and normalized to provide just an overall score for the assessment operation. This is compared to provide each and every answer as an input to a separate bin **206**. The program flows to a return block **412**.

[0051] Referring now to FIG. **5**, there is illustrated a flowchart depicting the overall consolidation process. This is initiated at a block **502** and then proceeds to a block **504** in order to process multiple tests for a specific pass, in this example as described hereinabove, for evaluating chronic pain in a particular patient. Again, this could be an assessment questionnaire, or it could be a lab tests such as liver test, as one example. There is then provided a filter in a process step **506** for the particular task to throw some tests out which are relatively minor as to the overall assessment of what type of compound would reduce opioid use, for example. If, for example, a liver panel were ordered, there may be certain aspects in the overall results of that test that are known to have a little correlation to that particular determination and these are filtered out. The program then flows to a process step **508** wherein, after the filtering step, the process scores the results of the tests with some particular algorithm, this being a consolidation algorithm. The process then flows to a process block **510** in order to generate a normalized score and then to a process block **512** in order to populate the associated bin and then to a return block **514**.

[0052] Referring now to FIG. **6**, there is illustrated a method for consolidating a liver panel, for example. In this example, there will be a plurality of test results in one column, this being the title of the test and this will provide the actual results of the tests as compared to the normal values expected for that test. In the consolidation process, each of the tests will be given a weight from 0 to 1, and then the figure value will be normalized to a value from 1 to 10, this being the score. For example, the first test, that labeled "ALT" for "Alanine Aminotransferase," which is an enzyme mainly found in the liver which is usually considered a good test for detecting hepatitis, is defined in the first column labeled "Test" with results provided therefore and a column showing the normal ranges, which is usually age-based and then the weight with a value between 0 to 1 and then a score from 1-10. Typical contents of a liver panel are as follows:

[0053] Alanine aminotransferase (ALT)—an enzyme mainly found in the liver; the best test for detecting hepatitis

[0054] Alkaline phosphatase (ALP)—an enzyme related to the bile ducts but also produced by the bones,

intestines, and during pregnancy by the placenta (afterbirth); often increased when bile ducts are blocked.

[0055] Aspartate aminotransferase (AST)—an enzyme found in the liver and a few other organs, particularly the heart and other muscles in the body

[0056] Bilirubin—two different tests of bilirubin often used together (especially if a person has jaundice): total bilirubin measures all the bilirubin in the blood; direct bilirubin measures a form that is conjugated (combined with another compound) in the liver.

[0057] Albumin—measures the main protein made by the liver; the level can be affected by liver and kidney function and by decreased production or increased loss.

[0058] Total protein (TP)—measures albumin and all other proteins in blood, including antibodies made to help fight off infections

[0059] Depending on the healthcare provider and the laboratory, other tests that may be included in a liver panel are:

[0060] Gamma-glutamyl transferase (GGT)—another enzyme found mainly in liver cells

[0061] Lactate dehydrogenase (LD)—an enzyme released with cell damage; found in cells throughout the body

[0062] Prothrombin time (PT)—the liver produces proteins involved in the clotting (coagulation) of blood; the PT measures clotting function and, if abnormal, may indicate liver damage.

[0063] Alpha-feto protein (AFP)—associated with regeneration or proliferation of liver cell

[0064] Autoimmune antibodies (e.g., ANA, SMA, anti-LKM-1)—associated with autoimmune hepatitis

[0065] When treating patients with opioid dependence, only certain tests resulting from the liver panel will be relevant or will be important to chronic pain. For example, patients receiving certain drugs such as, for example, buprenorphine, may have some adverse events associated with increases in serum aminotransferase levels. These may actually be the result of an individual with Hepatitis C. By understanding the comorbidity in such a situation, it is important to assign a weight the ALT and ALS test results. Another enzyme that is critical for the metabolism of some opioids is cytochrome P450, wherein a number of opioids are affected by this particular enzyme, such as codeine, hydrocodone, oxycodone, tramadol, fentanyl, and methadone. Again, this table of FIG. **6** is by way of example of any test that can be performed and importance of that particular test or group of tests that may have some importance to a chronic pain patient. There may be other portions of the liver panel, for example, that are more important to heart disease, such as lipid levels. These, of course, would be given little or no weight. A table for all of tests associated with the liver tests is as follows:

Type of liver condition or disease	Bilirubin	ALT and AST	ALP	Albumin	PT
Acute liver damage (due, for example, to infection, toxins or drugs, etc.)	Normal or increased usually after ALT and AST are already increased	Usually greatly increased (>10 times); ALT is usually higher than AST	Normal or only moderately increased	Normal	Usually normal
Chronic forms of various liver disorders	Normal or increased	Mildly or moderately increased; ALT is persistently increased	Normal to slightly increased	Normal	Normal
Alcoholic Hepatitis	Normal or increased	AST is moderately increased, usually at least twice the level of ALT	Normal or moderately increased	Normal	Normal
Cirrhosis	May be increased but this usually occurs later in the disease	AST is usually higher than ALT but levels are usually lower than in alcoholic disease	Normal or increased	Normal or decreased	Usually prolonged
Bile duct obstruction, cholestasis	Normal or increased; increased in complete obstruction	Normal to moderately increased	Increased; often greater than 4 times what is normal	Usually normal but if the disease is chronic, levels may decrease	Usually normal
Cancer that has spread to the liver (metastasized)	Usually normal	Normal or slightly increased	Usually greatly increased	Normal	Normal
Cancer originating in the liver (hepatocellular carcinoma, HCC)	May be increased, especially if the disease has progressed	AST higher than ALT but levels lower than that seen in alcoholic disease	Normal or increased	Normal or decreased	Usually prolonged

-continued

Type of liver condition or disease	Bilirubin	ALT and AST	ALP	Albumin	PT
Autoimmune	Normal or increased	Moderately increased; ALT usually higher than AST	Normal or slightly increased	Usually decreased	Normal

[0066] Note that only conditions that will be associated with a chronic pain patient and the reduction opioid dependency would be of interest.

[0067] Referring now to FIG. **7**, there is illustrated a diagrammatic view of how to consolidate all of these tests into a single number, as it may be that the necessary value to provide is a single score for a common test of, for example, a liver panel. In this example in FIG. **7**, there are provided a plurality of inputs **702** that each represent the results of a particular test. They are each processed through a particular weight value in a block **704** and then results summed together in a summing junction **706**. The output is then divided by the number of tests in a block **710** and normalized in a block **712**. This will provide a normalized value for the results, which can then be translated to a score from 1-10 in a block **714**. This is a value that is stored in the bin, as indicated by block **716**. Thus, all or a certain portion of the tests can be summed together and normalized, with the resulting score representing a portion of the PIN for the particular patient at the time that they are evaluated. It is again important to note that, each time a patient is evaluated, the results may be different. This is a function of the drugs that have been prescribed and the progression of their particular opioid dependence. For example, between two visits to a physician, the therapy prescribed by the physician may have reduced the opioid dependence by fifty percent. This would be ascertained through a questionnaire and that would be one input to the patient's PIN. This combined with the actual drugs being received, which is also part of the patient's PIN, would be provided as input to the database and comparing this particular patient's PIN with the results in the database, this being a global database. It is noted that one would expect a different result to be projected for the suggested therapy for that patient at that time. This is due to the fact that the first time the patient was evaluated and placed in the database, the suggestion might be to change the drug therapy. If the drug therapy has worked, the second time the information is placed into the database for comparison with the global database, a different result would come back.

[0068] Referring now to FIG. **8**, there is illustrated a block diagram of a global database that is a pain specific global database, i.e., the data provided thereto is specifically for the purpose of creating a model that will receive information from a particular patient, i.e., through that patient's particular PIN at the time of their evaluation, process it through the model based upon a large amount of data from other patients, and provide some type of suggested output. Here, the patient's PIN is provided in a block **802**, and all of the inputs comprise an input vector lines **803** to the local database **806**. This provides a resultant vector on output **810**. In this particular example, the resultant vector is the actual compound that would be suggested for a particular patient.

[0069] This particular output, that of the compound, is just one example of what the result could be. The particular compound could be a combination of multiple constituents that had been determined through an observational survey study which looked at patients over a certain age range having chronic musculoskeletal and neuropathic pain. As an example, a topical drug with the following compounding could be one form of a compound:

[0070] Flurbiprofen (20%)—anti-inflammatory

[0071] Amitrityline (5%)—Antidepressant

[0072] Magnesium Chloride (10%)—Salt

[0073] Gabapentine (6%)—Anti Seizure

[0074] Bupivicaine (2%)—Local Antiesthetic

[0075] Other transdermal gel

[0076] This particular compound combines an anti-inflammatory, antidepressant, a salt, an anti-seizure medicine, and a local anesthetic in a transdermal gel base. This provides the patient with a topical drug compound that can be used to reduce opioid dependence. Through the observational study, patients with a particular profile, i.e., a unique PIN at the time of the study, are evaluated at a later time to determine the results. The first result, of course, is the percentage of opioid reduction, and the second may be the actual percentage by weight of the compounds. The particular percentages noted hereinabove are percentages by weight which are determinable by the observational study as a normal value. It may be that the clinician selecting the original percentage values selected those based on known therapeutic results at a particular dosage. Also, price may be a factor.

[0077] Once a therapeutic level of a particular drug is determined to provide the therapeutic result of acceptable opioid reduction, and this can be done through trial and error via variation of the percentages, it is possible to vary those percentages based upon price. One formula for doing this is to vary the particular percentage weight of a particular compound from a minimum percentage weight to a maximum percentage weight. One formula for that is to take the norm, as determined through the observational study, and reduce it to 25% of the dosage on one end of the price perspective and multiplied by factor of two to determine the maximum dosage from a price perspective. This price can be one factor for determining the percentage weight of a particular compound. Additionally, substitutes for any of the drugs could be provided by utilizing generics or the such.

[0078] Thus, by utilizing a global database which has information stored therein that correlates particular information associated with the information from a PIN with a desired or predicted result, any PIN from a patient can be input to the global database and mapped through that database to provide a prediction. For example, the prediction may be that a particular PIN for a particular patient has been put in, and a particular compound has been put in, and this

information then "mapped" through global database process to provide an estimate of, or a prediction of, a potential reduction in opioid dependency. Alternatively, the information from a PIN of the patient could be input to the process in addition to a target range of opioid reduction and a suggestion or prediction made as to what compound, a topical drug compound for example, would be suggested. Since the model which the input information is mapped is based on a larger database of results, this will allow mapping based on a relatively nonlinear system.

[0079] Referring now to FIG. **9**, there is illustrated a diagrammatic view of one example of a model through which input data can be mapped to provide an estimate or a prediction on the output thereof. This is a neural network, which is a non-linear network. These type of networks can provide predictive results based on nonlinear system, wherein the human body and the overall evaluation thereof is a fairly nonlinear system. The neural network is comprised of an input layer **902** that receives an input vector **904** comprised of a plurality of input values, these being the values from the PIN. The input layer **902** is interconnected to one side of an intermediate layer **906**, which is interconnected to an output layer **908**. The output layer **908** is comprised of a vector **910** of a plurality of predicted outputs. The intermediate layer **906** and the interconnections thereto, once the interconnections are made, represent a model of the overall system, this model been trained upon the collected historical data.

[0080] Referring now to FIG. **10**, there is illustrated a more detailed diagram of a sample neural network. The input layer **902** is represented by two input nodes **1002** associated with a vector $\vec{x}$ comprised of two inputs. There are provided in the intermediate layer **906** three nodes **1004** to which each of the nodes **1002** is mapped. Thus, there will be three interconnections between each of the nodes **1002** and each of the nodes **1004**. Each of these interconnections is defined by interconnection line **1006**. Each of these interconnects has associated therewith a weight **1008**. Thus, the input vector $\vec{x}$ is comprised of two inputs x_1 and x_2 which each are interconnected to each of the nodes **1004**. If weight is defined as ω, then the formula for the input to each of the nodes **1004** for the first input vector x_1 will be: ωx_1. Each of the nodes **1004** in the intermediate layer **906** has associated therewith some type of function which is basically an activation function which "fires" this node to generate an output is typically a sigmoid function. Each of the nodes **1004** is individually mapped to a single output node **1010** that outputs an output the vector $\vec{y}$, it being noted that multiple output nodes **1010** could be provided with each of the nodes **1004** mapped to or interconnected to each of the nodes **1010** in a multiple note output. Each of these nodes **1004** is interconnected to the respective output node **1010** through a respective weight **1012** and a respective interconnect **1014**. These weights are learned through such techniques as back propagation. In back propagation, a set of data is provided wherein a known output for a set of data values for the input vector $\vec{x}$ is input to the network with an error determined between the mapping of this set of input data for that input vector through the intermediate layer **906** to the output. The weights are iteratively adjusted until the error is minimized. It is necessary to iteratively go through an entire set of data multiple times in order to reduce the error. This will result in a trained the model of the system represented by the database.

[0081] As an example, consider the situation wherein the desire is merely to determine for a given patient with a given PIN what their opioid reduction would be for a given compound. The PIN is input to the model, as well as the compound constituents and the percentages. The system will process this and output a predicted opioid reduction for that individual. Of course that means that the input vector upon which the model was trained was comprised of the elements of the PIN of patients in addition to the corresponding percentages of the compound. What that means is that the original database must have incorporated therein all the information from the patient in addition to the constituents associated with the compound at those percentages and some value of the opioid reduction determined therefrom. Thus, a patient would have a first PIN generated before taking a particular compound with a particular set of constituents at a particular defined percentage weight for each constituent and put the initial data from their initial PIN into the database in addition to the exact constituent distribution of the topical drug that they utilized and opioid reduction achieved after the use thereof. There, of course, would be required a large data in order to cover all possible combinations of patients and the different percentages by weight of the constituents in a particular compound. This is just one example.

[0082] In another example, the model can be trained to actually predict a compound, the constituents associated therewith and percentages by weight of the constituents contained therein. This would require, for a given set of data for a given input vector to be comprised of the patient PIN at the initial point in a study, a given opioid reduction for that patient after completion of the study, and a configured compound that was provided to the patient. Thereafter, all that is required is to put in the PIN for the new patient in addition to inputting therein a desired opioid reduction value or range of values as part of the input vector. Since the network is trained on that particular set of input vectors and that particular set of output vectors, a prediction can be made as to the percentage by weight of the constituents. There might, in fact, be required a separate model for each different compound such that the patient PIN can be processed through different compounds. In addition, once this particular patient with their initial PIN has been processed to the system and a prediction made as to what particular compound should be utilized, a later PIN from that patient and results can be input to the model for training there on.

[0083] Although the preferred embodiment has been described in detail, it should be understood that various changes, substitutions and alterations can be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

1. An opiate reduction treatment system, the system comprising:

a PIN generator for creating a Patient Identification Number (PIN) unique to a given patient, wherein the PIN includes one or more fields, and wherein the one or more fields each include a scored value converted from raw data corresponding to one or more test results, each scored value associated with a defined portion of a health profile of the given patient;

a database including test results for a plurality of PINs for a plurality of patients and associated compound constituents provided to each of the plurality of patients, and known treatments; and

a neural network, including:

an input layer configured to receive an output of a PIN for a given patient from the PIN generator and compound constituents as input values,

an output layer configured to provide an opioid reduction treatment prediction, and

an intermediate layer configured to store a representation of the database, and map the input layer to the output layer through the stored representation.

2. The system of claim **1**, wherein the scored value is created from one or more inputs from the raw data that are weighted according to associated test types and normalized.

3. The system of claim **1**, wherein the one or more fields of the PIN includes a code assigned to a patient.

4. The system of claim **3**, wherein the code assigned to the patient is a Patient Information Profile (PIP), wherein the PIP identifies the patient.

5. The system of claim **1**, wherein at least one of the one or more fields of the PIN corresponds to a particular test.

6. The system of claim **1**, wherein at least one of the one or more fields of the PIN corresponds to a compound formulation.

7. The system of claim **1**, wherein the scored value is a value within a number range.

8. The system of claim **7**, wherein the number range is a range between 1 and 10.

9. The system of claim **1**, wherein the PIN represents a patient pain profile at a first point in time.

10. The system of claim **9**, wherein the neural network is further configured to:

receive an output of another PIN representing a patient pain profile at a second point in time;

predict another opioid reduction treatment using the other PIN; and

store a revised treatment plan in the database.

11. A method for providing an opiate reduction treatment, comprising:

generating a Patient Identification Number (PIN) including one or more fields;

collecting raw data corresponding to one or more test results;

converting the raw data into a scored value;

storing the scored value in one of the one or more fields of the PIN;

predicting an opioid reduction treatment for a patient, including

providing as input values an output of the PIN and compound constituents to an input layer of a neural network,

applying, by an intermediate layer of the neural network, the input values and compound constituents information to a stored representation of a database, wherein the database includes test results for a plurality of PINs for a plurality of patients and associated compound constituents provided to each of the plurality of patients, and

generating, by an output layer of the neural network, an opioid reduction treatment prediction; and

delivering to a patient an opioid reduction treatment corresponding to the opioid reduction treatment prediction.

12. The method of claim **11**, wherein converting the raw data into the scored value includes:

creating one or more inputs from the raw data;

applying a weight to the one or more inputs to generate one or more weighted results, each one of the one or more weighted results corresponding to one of the one or more inputs;

summing the one or more weighted results to generate a summed output;

dividing the summed output by a number of tests to generate a result; and

translating the result into the scored value.

13. The method of claim **11**, wherein the one or more fields of the PIN includes a code assigned to a patient.

14. The method of claim **13**, wherein the code assigned to the patient is a Patient Information Profile (PIP), wherein the PIP identifies the patient.

15. The method of claim **11**, wherein at least one of the one or more fields of the PIN corresponds to a particular test.

16. The method of claim **11**, wherein at least one of the one or more fields of the PIN corresponds to a compound formulation.

17. The method of claim **11**, wherein the scored value is a value within a number range.

18. The method of claim **17**, wherein the number range is a range between 1 and 10.

19. The method of claim **11**, wherein the PIN represents a patient pain profile at a first point in time.

20. The method of claim **19**, further comprising:

providing an output of another PIN representing a patient pain profile at a second point in time;

predicting another opioid reduction treatment using the other PIN; and

storing a revised treatment plan in the database.

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